

FIRST REGULAR SESSION

# SENATE BILL NO. 369

95TH GENERAL ASSEMBLY

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INTRODUCED BY SENATOR STOUFFER.

Read 1st time February 12, 2009, and ordered printed.

TERRY L. SPIELER, Secretary.

1893S.011

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## AN ACT

To repeal sections 338.010, 338.013, 338.057, 338.220, and 338.337, RSMo, and to enact in lieu thereof four new sections relating to pharmacy.

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*Be it enacted by the General Assembly of the State of Missouri, as follows:*

Section A. Sections 338.010, 338.013, 338.057, 338.220, and 338.337, RSMo, are repealed and four new sections enacted in lieu thereof, to be known as sections 338.010, 338.013, 338.220, and 338.337, to read as follows:

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a specific pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, **pneumonia, and shingles** vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use

**EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.**

19 of auxiliary personnel under the direct supervision of a pharmacist from assisting  
20 the pharmacist in any of his duties. This assistance in no way is intended to  
21 relieve the pharmacist from his responsibilities for compliance with this chapter  
22 and he will be responsible for the actions of the auxiliary personnel acting in his  
23 assistance. This chapter shall also not be construed to prohibit or interfere with  
24 any legally registered practitioner of medicine, dentistry, podiatry, or veterinary  
25 medicine, or the practice of optometry in accordance with and as provided in  
26 sections 195.070 and 336.220, RSMo, in the compounding or dispensing of his own  
27 prescriptions.

28         2. Any pharmacist who accepts a prescription order for a medication  
29 therapeutic plan shall have a written protocol from the physician who refers the  
30 patient for medication therapy services. The written protocol and the prescription  
31 order for a medication therapeutic plan shall come from the physician only, and  
32 shall not come from a nurse engaged in a collaborative practice arrangement  
33 under section 334.104, RSMo, or from a physician assistant engaged in a  
34 supervision agreement under section 334.735, RSMo.

35         3. Nothing in this section shall be construed as to prevent any person,  
36 firm or corporation from owning a pharmacy regulated by sections 338.210 to  
37 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

38         4. Nothing in this section shall be construed to apply to or interfere with  
39 the sale of nonprescription drugs and the ordinary household remedies and such  
40 drugs or medicines as are normally sold by those engaged in the sale of general  
41 merchandise.

42         5. No health carrier as defined in chapter 376, RSMo, shall require any  
43 physician with which they contract to enter into a written protocol with a  
44 pharmacist for medication therapeutic services.

45         6. This section shall not be construed to allow a pharmacist to diagnose  
46 or independently prescribe pharmaceuticals.

47         7. The state board of registration for the healing arts, under section  
48 334.125, RSMo, and the state board of pharmacy, under section 338.140, shall  
49 jointly promulgate rules regulating the use of protocols for prescription orders for  
50 medication therapy services and administration of viral influenza vaccines. Such  
51 rules shall require protocols to include provisions allowing for timely  
52 communication between the pharmacist and the referring physician, and any  
53 other patient protection provisions deemed appropriate by both boards. In order  
54 to take effect, such rules shall be approved by a majority vote of a quorum of each

55 board. Neither board shall separately promulgate rules regulating the use of  
56 protocols for prescription orders for medication therapy services and  
57 administration of viral influenza vaccines. Any rule or portion of a rule, as that  
58 term is defined in section 536.010, RSMo, that is created under the authority  
59 delegated in this section shall become effective only if it complies with and is  
60 subject to all of the provisions of chapter 536, RSMo, and, if applicable, section  
61 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any  
62 of the powers vested with the general assembly pursuant to chapter 536, RSMo,  
63 to review, to delay the effective date, or to disapprove and annul a rule are  
64 subsequently held unconstitutional, then the grant of rulemaking authority and  
65 any rule proposed or adopted after August 28, 2007, shall be invalid and void.

66 8. The state board of pharmacy may grant a certificate of medication  
67 therapeutic plan authority to a licensed pharmacist who submits proof of  
68 successful completion of a board-approved course of academic clinical study  
69 beyond a bachelor of science in pharmacy, including but not limited to clinical  
70 assessment skills, from a nationally accredited college or university, or a  
71 certification of equivalence issued by a nationally recognized professional  
72 organization and approved by the board of pharmacy.

73 9. Any pharmacist who has received a certificate of medication therapeutic  
74 plan authority may engage in the designing, initiating, implementing, and  
75 monitoring of a medication therapeutic plan as defined by a prescription order  
76 from a physician that is specific to each patient for care by a specific pharmacist.

77 10. Nothing in this section shall be construed to allow a pharmacist to  
78 make a therapeutic substitution of a pharmaceutical prescribed by a physician  
79 unless authorized by the written protocol or the physician's prescription order.

338.013. 1. Any person desiring to assist a pharmacist in the practice of  
2 pharmacy as defined in this chapter shall apply to the board of pharmacy for  
3 registration as a pharmacy technician. Such applicant shall be, at a minimum,  
4 legal working age and shall forward to the board the appropriate fee and written  
5 application on a form provided by the board. Such registration shall be the sole  
6 authorization permitted to allow persons to assist licensed pharmacists in the  
7 practice of pharmacy as defined in this chapter.

8 2. The board may refuse to issue a certificate of registration as a  
9 pharmacy technician to an applicant that has been adjudicated and found guilty,  
10 or has entered a plea of guilty or nolo contendere, of a violation of any state,  
11 territory or federal drug law, or to any felony or has violated any provision of

12 subsection 2 of section 338.055. Alternately, the board may issue such person a  
13 registration, but may authorize the person to work as a pharmacy technician  
14 provided that person adheres to certain terms and conditions imposed by the  
15 board. The board shall place on the employment disqualification list the name  
16 of an applicant who the board has refused to issue a certificate of registration as  
17 a pharmacy technician, or the name of a person who the board has issued a  
18 certificate of registration as a pharmacy technician but has authorized to work  
19 under certain terms and conditions. The board shall notify the applicant of the  
20 applicant's right to file a complaint with the administrative hearing commission  
21 as provided by chapter 621, RSMo.

22 3. If an applicant has submitted the required fee and an application for  
23 registration to the board of pharmacy, the applicant for registration as a  
24 pharmacy technician may assist a licensed pharmacist in the practice of  
25 pharmacy as defined in this chapter [for a period of up to ninety days prior to the  
26 issuance of a certificate of registration]. The applicant shall keep a copy of the  
27 submitted application on the premises where the applicant is employed. [When]  
28 If the board refuses to issue a certificate of registration as a pharmacy technician  
29 to an applicant, the applicant shall immediately cease assisting a licensed  
30 pharmacist in the practice of pharmacy.

31 4. A certificate of registration issued by the board shall be conspicuously  
32 displayed in the pharmacy or place of business where the registrant is employed.

33 5. Every pharmacy technician who desires to continue to be registered as  
34 provided in this section shall, within thirty days before the registration expiration  
35 date, file an application for the renewal, accompanied by the fee prescribed by the  
36 board. [No registration as provided in this section shall be valid if the  
37 registration has expired and has not been renewed as provided in this subsection]  
38 **The registration shall lapse and become null and void thirty days after**  
39 **the expiration date.**

40 6. The board shall maintain an employment disqualification list. No  
41 person whose name appears on the employment disqualification list shall work  
42 as a pharmacy technician, except as otherwise authorized by the board. The  
43 board may authorize a person whose name appears on the employment  
44 disqualification list to work or continue to work as a pharmacy technician  
45 provided the person adheres to certain terms and conditions imposed by the  
46 board.

47 7. The board may place on the employment disqualification list the name

48 of a pharmacy technician who has been adjudicated and found guilty, or has  
49 entered a plea of guilty or nolo contendere, of a violation of any state, territory  
50 [of], or federal drug law, or to any felony or has violated any provision of  
51 subsection 2 of section 338.055.

52 8. After an investigation and a determination has been made to place a  
53 person's name on the employment disqualification list, the board shall notify such  
54 person in writing mailed to the person's last known address [that]:

55 (1) **That** an allegation has been made against the person, the substance  
56 of the allegation and that an investigation has been conducted which tends to  
57 substantiate the allegation;

58 (2) **That** such person's name has been added in the employment  
59 disqualification list of the board;

60 (3) The consequences to the person of being listed and the length of time  
61 the person's name will be on the list; and

62 (4) The person's right to file a complaint with the administrative hearing  
63 commission as provided in chapter 621, RSMo.

64 9. The length of time a person's name shall remain on the disqualification  
65 list shall be determined by the board.

66 10. No hospital or licensed pharmacy shall knowingly employ any person  
67 whose name appears on the employee disqualification list, except that a hospital  
68 or licensed pharmacy may employ a person whose name appears on the  
69 employment disqualification list but the board has authorized to work under  
70 certain terms and conditions. Any hospital or licensed pharmacy shall report to  
71 the board any final disciplinary action taken against a pharmacy technician or  
72 the voluntary resignation of a pharmacy technician against whom any complaints  
73 or reports have been made which might have led to final disciplinary action that  
74 can be a cause of action for discipline by the board as provided for in subsection  
75 2 of section 338.055. Compliance with the foregoing sentence may be interposed  
76 as an affirmative defense by the employer. Any hospital or licensed pharmacy  
77 which reports to the board in good faith shall not be liable for civil damages.

338.220. 1. It shall be unlawful for any person, copartnership,  
2 association, corporation or any other business entity to open, establish, operate,  
3 or maintain any pharmacy as defined by statute without first obtaining a permit  
4 or license to do so from the Missouri board of pharmacy. **A permit shall not be**  
5 **required for an individual licensed pharmacist to perform**  
6 **nondispensing activities outside of a pharmacy, subject to rules**

7 **established by the board. A permit shall not be required for an**  
8 **individual licensed pharmacist to administer drugs, vaccines, and**  
9 **biologicals by protocol, as permitted by law, outside of a pharmacy.** The  
10 following classes of pharmacy permits or licenses are hereby established:

- 11 (1) Class A: Community/ambulatory;
- 12 (2) Class B: Hospital outpatient pharmacy;
- 13 (3) Class C: Long-term care;
- 14 (4) Class D: Nonsterile compounding;
- 15 (5) Class E: Radio pharmaceutical;
- 16 (6) Class F: Renal dialysis;
- 17 (7) Class G: Medical gas;
- 18 (8) Class H: Sterile product compounding;
- 19 (9) Class I: Consultant services;
- 20 (10) Class J: Shared service;
- 21 (11) Class K: Internet;
- 22 (12) Class L: Veterinary.

23 2. Application for such permit or license shall be made upon a form  
24 furnished to the applicant; shall contain a statement that it is made under oath  
25 or affirmation and that its representations are true and correct to the best  
26 knowledge and belief of the person signing same, subject to the penalties of  
27 making a false affidavit or declaration; and shall be accompanied by a permit or  
28 license fee. The permit or license issued shall be renewable upon payment of a  
29 renewal fee. Separate applications shall be made and separate permits or  
30 licenses required for each pharmacy opened, established, operated, or maintained  
31 by the same owner.

32 3. All permits, licenses or renewal fees collected pursuant to the  
33 provisions of sections 338.210 to 338.370 shall be deposited in the state treasury  
34 to the credit of the Missouri board of pharmacy fund, to be used by the Missouri  
35 board of pharmacy in the enforcement of the provisions of sections 338.210 to  
36 338.370, when appropriated for that purpose by the general assembly.

37 4. Class L: veterinary permit shall not be construed to prohibit or  
38 interfere with any legally registered practitioner of veterinary medicine in the  
39 compounding or dispensing of their own prescriptions.

40 5. Notwithstanding any other law to the contrary, the provisions of this  
41 section shall not apply to the sale, dispensing, or filling of a pharmaceutical  
42 product or drug used for treating animals.

338.337. It shall be unlawful for any out-of-state wholesale drug distributor or out-of-state pharmacy acting as a distributor to do business in this state without first obtaining a license to do so from the board of pharmacy and paying the required fee. Application for an out-of-state wholesale drug distributor's license under this section shall be made on a form furnished by the board. The issuance of a license under sections 338.330 to 338.370 shall not change or affect tax liability imposed by the Missouri department of revenue on any out-of-state wholesale drug distributor or out-of-state pharmacy. Any out-of-state wholesale drug distributor that is a drug manufacturer and which produces and distributes from a facility which has been inspected and approved by the Food and Drug Administration within the last two years and which is licensed by the state in which the distribution facility is located need not be licensed as provided in this section but such out-of-state distributor shall register its business name and address with the board of pharmacy and pay a filing fee [of ten dollars] **in an amount established by the board.**

[338.057. The board of pharmacy shall publish a list of drug products for which substitution as provided in section 338.056 shall not be permitted. The list of drug products to be included on this list shall be based upon a joint determination made by the department of health and senior services, the state board of registration for the healing arts, and the state board of pharmacy. The board of pharmacy shall publish the list not less often than semiannually, and shall publish amendments to the list as required.]

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